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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,891	08/02/2001	Brigitte Bathe	211714US0X	5791
22850	7590	12/02/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				FRONDA, CHRISTIAN L
ART UNIT		PAPER NUMBER		
		1652		

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/919,891	BATHE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 19 August 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 35-81 is/are pending in the application.  
 4a) Of the above claim(s) 56-79 is/are withdrawn from consideration.  
 5) Claim(s) 35-49,80 and 81 is/are allowed.  
 6) Claim(s) 50 and 52-55 is/are rejected.  
 7) Claim(s) 51 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 02 August 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 07/14/2004.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

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## DETAILED ACTION

1. In the AMENDMENT dated 08/19/2004, applicants have cancelled claims 1-34 and added new claims 35-81.
2. Claims 35-55, 80, and 81 contain subject matter that corresponds to the elected invention of Group I. Newly submitted claims 56-79 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The subject matter of claims 56-79 correspond to the non-elected invention of Group III, which is directed toward a process for making L-amino acids. Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polynucleotide in a recombinant process for the production of homocysteine methyltransferase .

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-79 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claims 35-55, 80, and 81 are under consideration in this Office Action.
4. The rejection of claim 9 under 35 U.S.C. 112, first paragraph, as lacking an enabling deposit of the recited *Escherichia coli* strain DSM 14354 has been withdrawn in view of applicants' cancellation of the claim; and applicants' statement that in accordance with the conditions of the deposit under the terms of the Budapest Treaty, all restrictions on the public availability of the *Escherichia coli* strain DSM 14354 will be irrevocably removed upon granting of a patent to the instant application. Accordingly, claim 80 which recites *Escherichia coli* strain DSM 14354 meets the requirements of U.S.C. 112, first paragraph.
5. The rejection of claims 1-3, 5, and 8 under 35 U.S.C. 112, second paragraph, as being indefinite is moot and has been withdrawn in view of applicants' cancellation of these claims.
6. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) is moot and has been withdrawn in view of applicants' cancellation of these claims.

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***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 50 and 52-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence that is at least 95% identical SEQ ID NO:2 or an isolated polynucleotide which is at least 95% identical to SEQ ID NO: 1; does not reasonably provide enablement for an isolated polynucleotide which is at least 90% identical to SEQ ID NO: 1 and encodes a protein having homocysteine methyltransferase activity.

Applicants' arguments filed 08/19/2004 have been fully considered but they are not persuasive. Applicants' position is that the specification enables and describes the representative genus of polynucleotides that encode proteins with at least 90% identity to SEQ ID NO: 1. The Examiner respectfully disagrees for reason of record as supplemented below.

SEQ ID NO: 1 is disclosed as consisting of 4301 nucleotides. Thus, the claims encompass polynucleotides that have 3871 nucleotides that are identical to SEQ ID NO: 1 and up to 430 nucleotides that are different (substitutions, deletions, or insertions with any nucleotide) from SEQ ID NO: 1 since the claim recites the limitation of 90% identity to SEQ ID NO: 1.

Neither the specification nor the general knowledge of those skilled in the art provide guidance or prediction regarding the specific 430 nucleotides in SEQ ID NO: 1 which can be changed and still encode a functional homocysteine methyltransferase. The specification does not provide working examples for selecting the specific 430 nucleotides in SEQ ID NO: 1 in SEQ ID NO: 1.

Since neither the specification nor information known in the art provide guidance or prediction for the specific nucleotides that can be changed and still encode a functional homocysteine methyltransferase, one must perform an enormous amount of trial and error experimentation to determine which 430 nucleotides in SEQ ID NO: 1 can be changed to make a polynucleotide that is at least 90% identical to SEQ ID NO: 1 and yet has the property of encoding a functional homocysteine methyltransferase. Such trial and error experimentation is well outside the realm of routine experimentation and entails selecting any 430 nucleotides in SEQ ID NO: 1 to modify, searching and screening for the type of modification to perform on the selected nucleotides (deletion, insertion, substitution, additions or combinations thereof), and expressing the polynucleotide to determine whether the polynucleotide still has the property of encoding a functional homocysteine methyltransferase. Teaching regarding

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screening and searching for the claimed invention using assays stated in the specification is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific 430 nucleotides which can be changed in SEQ ID NO: 1 which does not affect the property of encoding a functional homocysteine methyltransferase. Without such a guidance, the amount of experimentation left to those skilled in the art to make the claimed invention is undue and well outside of routine experimentation. Claims 52-55 which depend from claim 50 are also rejected because they do not correct the defect of claim 50.

Regarding claim 81, the claim encompasses any polynucleotide consisting of 100 consecutive nucleotides of SEQ ID NO: 1 with no specific function. Without a recitation of a particular function, one skilled in the art to which it pertains, or with which it is most nearly connected, would not be able to use the claimed polynucleotide consisting of 100 consecutive nucleotides of SEQ ID NO: 1,

9. Claim 81 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 81 is a genus claims that are directed toward all possible polynucleotides consisting of 100 consecutive nucleotides of SEQ ID NO: 1. The scope of the claim includes many polynucleotides with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members is permitted.

The disclosed polynucleotide having a nucleotide sequence of SEQ ID NO: 1 encoding a homocysteine methyltransferase is not representative of the entire claimed genus since members of the claimed genus encompass polynucleotides that have other biological functions. There is no recitation of any particular structure to function/activity relationship in claim 81 that clarify what common attributes are shared by members of the claimed genus.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

### ***Conclusion***

10. Claims 35-49, and 80 are allowed.

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11. Claims 51 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

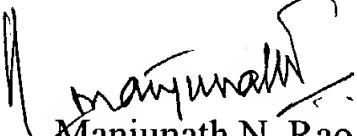
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L. Fronda  
Examiner  
Art Unit 1652



Manjunath N. Rao  
Primary Examiner  
Art Unit 1652